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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SMITH, CAROLYN L	

ART UNIT	PAPER NUMBER
1631	17

DATE MAILED: 04/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

S.M.

Office Action Summary	Application No.	Applicant(s)	
	09/910,345	SHEPARD ET AL.	
	Examiner	Art Unit	
	Carolyn L Smith	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-81 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-81 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The art unit designated for this application has changed. Applicant(s) are hereby informed that future correspondence should be directed to Art Unit 1631.

Restriction/Election:

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-6, drawn to a method for inhibiting the proliferation of a pathogen or a cell infected with a pathogen, classified in class 514, subclass 2. If this Group is elected, then THREE of the below summarized specie elections are also required.

II. Claims 7-17, drawn to a method for screening for a therapeutic agent that selectively inhibits the growth of pathogen or a pathogen-infected cell, classified in class 424, subclass 9.2. If this Group is elected, then THREE of the below summarized specie elections are also required.

III. Claims 18-67, drawn to a method, system, and computer program product for identifying drug targets, classified in class 702, subclass 19. If this Group is elected, then TWO of the below summarized specie elections are also required.

IV. Claims 68-74, drawn to a method for alleviating symptoms of a disease, classified in class 514, subclass 2. If this Group is elected, then TWO of the below summarized specie elections are also required.

V. Claims 75-81, drawn to a method for treating an infection caused by iECTA enzyme expression, classified in class 514, subclass 2. If this Group is elected, then TWO of the below summarized specie elections are also required.

Specie Election Requirements for Groups I-V:

This application contains claims directed to the following patentably distinct species of the claimed invention:

First Specie Election Requirement for **Groups I, II, IV, and V**:

Specie A: selection of one iECTA enzyme listed in Figures 7A and 7B

Second Specie Election Requirement for **Groups I and II**:

Specie B: a pathogen which is a bacterium

Specie C: a pathogen which is a parasite

Specie D: a pathogen which is a rickettesia

Specie E: a pathogen which is a virus

Specie F: a pathogen which is a fungus

Third Specie Election Requirement for **Groups I and II**:

Specie G: method involving *in vitro* techniques

Specie H: method involving *in vivo* techniques

First Specie Election Requirement for **Group III**:

Specie I: a target organism which is a bacterium

Specie J: a target organism which is a parasite

Specie K: a target organism which is a rickettesia

Specie L: a target organism which is a virus

Specie M: a target organism which is a fungus

Second Specie Election Requirement for **Group III**:

Specie N: an alignment search algorithm which is a Needleman-Wunsch global alignment algorithm

Specie O: an alignment search algorithm which is a Smith-Waterman local alignment algorithm

Specie P: an alignment search algorithm which is a "FAST" algorithm

Specie Q: an alignment search algorithm which is a BLAST algorithm

Second Specie Election Requirement for **Groups IV and V**:

Specie R: a organism which is a bacterium

Specie S: a organism which is a parasite

Specie T: a organism which is a rickettesia

Specie U: a organism which is a virus

Specie V: a organism which is a fungus

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species within each requirement for the appropriate Group elected to which the claims shall be restricted if no generic claim is finally held to be allowable. The distinctness of each iECTA enzyme (Groups 1, II, IV, and V) is because each enzyme features different characteristics with different structures and functions. The distinctness of the five pathogens/target organisms/organism (Groups I-V) is because each pertains to organisms with distinctly different characteristics. The distinctness of

the *in vitro* versus *in vivo* methods (Groups I and II) is because each type of technique features distinctly different method steps that are not required one for the other. The distinctness of the four alignment search algorithms (Group III) is because each uses distinctly different parameters and method steps to achieve their goals. These separate chemical and entity types are often separately characterized and published in literature, thus adding to the search burden if all species were searched together. Also, processing that may connect two species does not prevent them from being considered distinct because enough processing can result in the production of any composition from another composition as long as the processing is not limiting in occurrences such as subtractions, additions, and enzymatic action. Thus, the above-mentioned species within Groups I and II are independent and/or distinct invention types for restriction purposes.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to

be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

These groups are distinct, each from the other because of the following reasons:

Groups I-V are different and distinct because they each are based on critically different features. The critical features of Group I are based on a method to inhibit pathogen or pathogen-infected cell proliferation through the use of an effectively known iECTA prodrug. The critical features of Group II are based on a method of screening for agents for possible efficacy in inhibiting pathogen or pathogen-infected cell growth. The critical features of Group III are based on a method of identifying drug targets via computer techniques not found in other Groups. The critical features of Group IV are based on a method of alleviating symptoms of a disease. The critical features of Group V are based on a method of treating infections caused by an iECTA enzyme expression. These separate entity types are often separately characterized and published in literature, thus adding to the search burden if all Groups were searched together. Thus, the five Groups are independent and/or distinct invention types for restriction purposes.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement may be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (703) 308-6043. The examiner can normally be reached Monday through Friday from 8 A.M. to 4:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

April 8, 2003

ARDIN H. MARSCHEL
PRIMARY EXAMINER